Engagement Report

Topic details

Title of policy or policy statement:	MR-guided laser interstitial thermal therapy for treatment of epileptogenic zones in children and adults with refractory focal epilepsy
Programme of Care:	Trauma
Clinical Reference Group:	Neurosurgery
URN:	2006

1. Summary

This report summarises the feedback NHS England received from engagement during the development of this policy proposition, and how this feedback has been considered. There have been 5 forms completed and received.

2. Background

MRgLITT, also known as 'laser interstitial thermal therapy' (LITT), is a minimally invasive treatment which can be used in focal refractory epilepsy. Stereotactic neurosurgical technique is used to guide a 3mm diameter fibreoptic laser to the target area of the brain. Under continuous MRI monitoring, laser energy is applied to the target area to destroy the part of the brain causing seizure activity. It is safer than open neurosurgery as there is less risk of collateral damage to other structures in the brain. Open surgery causes damage along the operative pathway to access the part to be removed, which is mitigated by this minimally invasive approach.

Patients would normally be discharged home 24-48 hours after the MRgLITT procedure and be expected to resume normal activities and employment in 7 days, compared to a 5-10 day inpatient stay and a 2 month recuperation period after conventional neurosurgery.

This policy proposition has been developed by a Policy Working Group made up of a Clinical Lead, a Public Health Lead, a Lead Commissioner, a patient and public voice partner, and 4 clinicians with experience in managing epilepsy.

3. Engagement

NHS England has a duty under Section 13Q of the NHS Act 2006 (as amended) to 'make arrangements' to involve the public in commissioning. Full guidance is available in the Statement of Arrangements and Guidance on Patient and Public Participation in

Commissioning. In addition, NHS England has a legal duty to promote equality under the Equality Act (2010) and reduce health inequalities under the Health and Social Care Act (2012).

The policy proposition was sent for stakeholder testing for 2 weeks from 22/04/2022 to 08/05/2022. The comments have then been shared with the Policy Working Group to enable full consideration of feedback and to support a decision on whether any changes to the proposition might be recommended.

Respondents were asked the following questions:

- Do you support the proposition for MR-guided laser interstitial thermal therapy for treatment of epileptogenic zones in children and adults with refractory focal epilepsy to be available through routine commissioning based on the evidence review and within the criteria set out in this document?
- Do you believe that there is any additional information that we should have considered in the evidence review? If so, please give brief details.
- Do you believe that there are any potential positive and/or negative impacts on patient care as a result of making this treatment option available? If so, please give details.
- Do you have any further comments on the proposition? If Yes, please describe below, in no more than 500 words, any further comments on the proposed changes to the document as part of this initial 'sense check'.
- Please declare any conflict of interests relating to this document or service area.
- Do you support the Equality and Health Inequalities Impact Assessment?

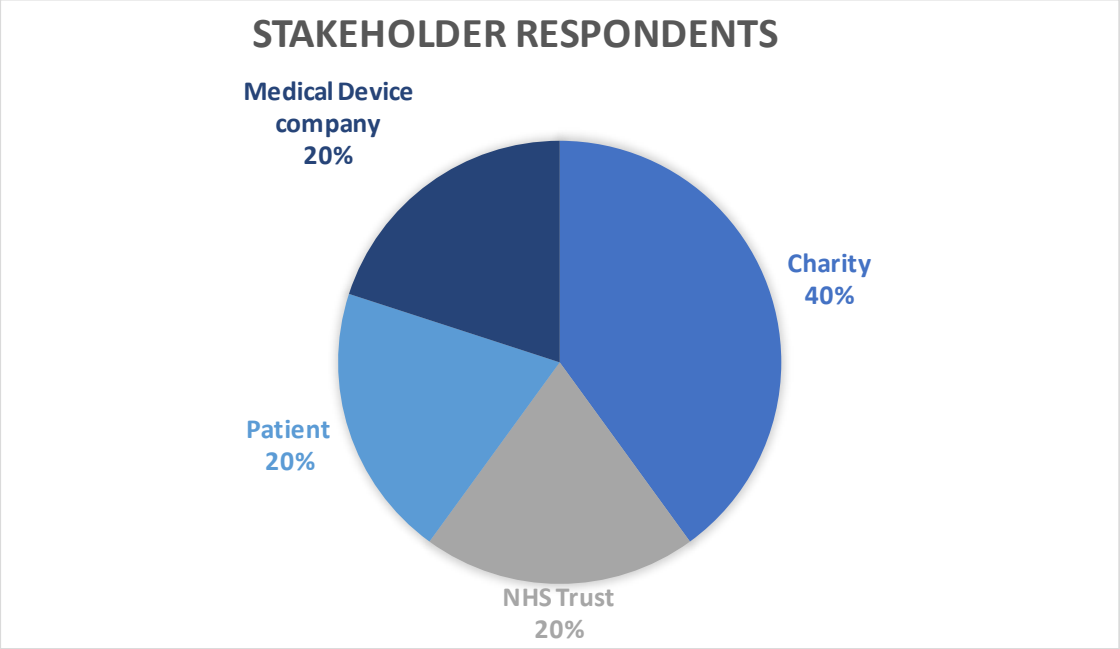
A 13Q assessment has been completed following stakeholder testing.

The Programme of Care has decided that the proposition offers a clear and positive impact on patient treatment, by potentially making a new treatment available which widens the range of treatment options without disrupting current care or limiting patient choice, and therefore further public consultation was not required. This decision has been assured by the Patient Public Voice Advisory Group.

4. Engagement Results

There were 5 responses received:

- 2 charities related to epilepsy
- 1 NHS Trust
- 1 patient with lived experience of epilepsy
- 1 medical device company



In line with the 13Q assessment it was deemed that further public consultation was not required.

5. How has feedback been considered?

Responses to engagement have been reviewed by the Policy Working Group and the Trauma PoC. All the respondents supported the policy proposition.

The following themes were raised during engagement:

Key themes in feedback	NHS England Response
Relevant Evidence	
General agreement that there is enough evidence to make the treatment available at this time. Across 2 stakeholders there were 11 extra papers presented which have been published since the evidence review. One stakeholder also raised that it would be helpful to include within the policy the current prices offered by the supplier. They also asked whether all children's epilepsy surgery centres would be funded to perform MRgLITT and how many centres are being planned.	Thank you for your response. These have been reviewed by the Public Health lead attached to this policy proposition to see if they materially change the routine commissioning position. They do not materially impact the commissioning position. The full assessment of these can be seen in the associated report for additional evidence. The cost of the intervention does not sit within the policy proposal document but is assessed as part of the financial build later in the process. The answer to the additional questions posed here will form part of the commissioning plan for this proposition.
Potential positive and negative impacts on patient care	
Stakeholders felt that making this procedure available at this time would have an overwhelmingly positive impact. It would offer equity of access to a potentially curative surgical option for the treatment of refractory focal	Thank you for your response. Provider organisations are required to assure themselves that patients are adequately followed up with annual neurology follow up as default, including assessment for

epilepsy for those in whom open neurosurgery is contraindicated or considered high risk. They also noted that MRgLITT offers a cure with much less morbidity than conventional neurosurgery: reduced hospital stay, reduced pain and reduced risk of infection, quicker return to work, less neurological and neuropsychological deficits, as a craniotomy and creation of a surgical access channel to the area to be removed or ablated is not needed. One stakeholder raised that this could be a challenging service to set up, but agreed it was a positive necessary development. They stressed the importance of the collaborative audit process outlined within the policy. One stakeholder raised the risk of missing long term outcomes and that this needs to be assured against. They also advised that from a patient safety perspective the MDT decision process also needs to be included within an audit trail.	long-term complications. It is recommended that this is for 20 years. The wording in the policy proposition has been updated to ensure this is clear. Providers are also required to ensure processes are in place to track decisions to treat, including the MDT outcomes.
Potential positive impacts on the health system	
Stakeholders recognised the likely cost saving implications of MRgLITT in comparison to open neurosurgery due to the shorter lengths of stay and recovery times. They also recognised that there are long waiting lists for open neurosurgery and providing this as an alternative would provide another treatment option for some of the patients on these lists.	Thank you for your response.
Potential impact on equality and health inequalities	
Stakeholders recognised that there is a current inequity of access to a potentially curative surgical option which this policy is hoping to address. They raised that 1 in 5 people with epilepsy also have a learning disability and that the more severe the learning disability, the more likely the person is to have epilepsy.	Thank you for your response. An update to the EHIA to include this information on learning disability in epilepsy has been made.
Changes/addition to patient impact summary	
Stakeholders raised the impact of open neurosurgery for patients who have this treatment rather than MRgLITT. They also reflected the impact of living with uncontrolled refractory epilepsy for those who cannot have surgical treatment. They also advised on the increased risk of suicide and accidental death compared to the general population for those who live with uncontrolled epilepsy.	Thank you for your response. The patient impact summary focusses on the condition rather than the available treatments, which is why there is not comments on the effects of open neurosurgery. It is also important to note that MRgLITT is not purely an alternative to open neurosurgery but will be an option also to those patients who

	do not have open neurosurgery as an option.
	Thank you for your comments. Update to the Patient Impact Summary on the higher likelihood of suicide and accidental death in this group.

6. Has anything been changed in the policy proposition as a result of the stakeholder testing and consultation?

There following change(s) based on the engagement responses has (have) been made to the policy proposition:

- Minor update to the Patient Impact Assessment to highlight the increased risk of death by suicide and death as a result of seizures in this patient group.
- Minor update to the Equality and Healthy Inequalities Assessment to highlight the increased rate of epilepsy amongst those with learning disabilities
- Minor update to the policy proposition to highlight need for follow up to 20 years post treatment.

7. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final policy proposition?

No – all remaining issues resolved.